K111973

Nucletron

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SEP 2 1 2011

Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(k) Summary

June 29, 2011

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	7021 Columbia Gateway Drive Suite 200 21046 Columbia MD
Phone:	443 545 2182
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Correspondent:	Michael Paul Regulatory Affairs/Quality Assurance Manager

New Device Name:

Trade/Proprietary Name:	Vaginal CT/MR Multi Channel Applicator Set
Common/Usual Name:	Gynecological Brachytherapy applicator
Classification Name:	Remote controlled radionuclide applicator system accessory
Classification:	21Cfr892.5700 Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Miami Vaginal Applicator Set	K953946

Description:
The Vaginal CT/MR Multi Channel Applicator Set is a modification of the Miami Vaginal Applicator Set. It is intended for gynecologic brachytherapy of the vagina, cervix and endometrium. The applicator consists of a central channel and surface channels, which are equally spaced around the surface of the cylinder.

The vaginal cylinder is several sizes, each diameter with a specified number of surface channels. The surface channels follow the shape of the cylinder's dome. By selectively and individually loading these channels, the dose can be directed laterally and sculpted to the required shape, for instance for treatment of asymmetrically located tumors.

The Vaginal CT/MR Multi Channel Applicator Set can be used in combination with X-ray, CT and MRI. Markers for the treatment channels are available to assist in visualization of the source path on the acquired images.

The devices are used as accessories to Nucletron afterloaders.

Intended use:

The Vaginal CT/MR Multi Channel Applicator Set is intended for gynecologic Brachytherapy treatment of the vagina, cervix and endometrium.

Summary of technological considerations:
Intended use, operating principle, design, performance and technological characteristics of the modified device are the same as or similar to the legally marketed device. The modified device can be used with CT and MRI through use of other materials. Some parts of the modified device are single use.

Summary of testing:
Validation of sterilization processes and biocompatibility is provided. Bench testing shows that the device meets its performance requirements, and that the device performance is equivalent to the Miami Vaginal Applicator Set.

Conclusion:

Nucletron considers the Vaginal CT/MR Multi Channel Applicator Set to be substantially equivalent to legally marketed predicate device through the data and information presented. No safety or effectiveness issues were identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr.Michael Paul
Regulatory Affairs/Quality Assurance Manager
Nucletron Corporation
7021 Columbia Gateway Drive, Suite 200
COLUMBIA MD 21046-2133

SEP 21 2011

Re: K111973
Trade/Device Name: Vaginal CT/MR Multi Channel Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: August 30, 2011
Received: August 31, 2011

Dear Mr. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K111973

Device Name Vaginal CT/MR Multi Channel Applicator Set

Indications for Use The Vaginal CT/MR Multi Channel Applicator Set is intended for gynecologic Brachytherapy treatment of the vagina, cervix and endometrium.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111973